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Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville  
MD, 20852

3319 Sept 9/99 SEP 17 19:54

RE: Docket no. 98N-1215

Gentlemen,

I am writing to express my concerns regarding the "Proposed FDA regulations for foreign establishment registration and listing".

As a small Canadian manufacturer of A.D.L. items (Assistive Devices for Living) we would find the proposed regulations an onerous task, in effect a non-tariff barrier. The items we manufacture fall into FDA class 1 products. These are Homecare products that allow a person with a disability to remain living independently at home. Our products are designed to allow the user to make the most of his/her abilities and thus gain the maximum degree of independence. Governments should be cognizant of the fact that Home Care products keep people at home and out of government funded institutions. Increasing our cost of doing business in this product range only increases the cost to the user. When this increased cost puts the item out of the financial reach of the person in need, not only does the individual loose, but so does the government, who will end up funding the eventual care of another person who can no longer care for themselves.

We currently have about 1000 products in our line. We ship to both the small moma popa Home Healthcare Store and to large distributors. The distributors buy large volumes of specific items but the dealers may buy any of the 1000 items in the line. These items are predominantly small inexpensive items such as adapted tableware (FDA class 1). Appointing an agent to represent Parsons A.D.L. Inc. would be a definite problem. The product line is varied and the dollar volume is low. How could we afford to hire an agent and who, as an agent would be interested in properly representing such a small company with a low dollar volume. Our total company sales into the U.S.A. this year will be about \$232,000 in U.S. dollars. Of this about \$58,000 goes to small dealers, the rest is to larger distributors.

We currently ship our products to many countries such as: England, Denmark, France, Italy, Australia, Japan and others. Not one of these has presented us with a potential restriction such as those proposed by the FDA. In today's world economy, and with Canada / U.S. Free Trade in effect, I feel that these proposals represent a barrier to trade with a country which is supposed to be a "Trade partner" while the "Non-partner" countries present no such restrictions.

Yours truly,

*Ron Parsons*

President

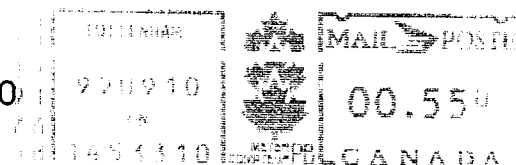
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INDEPENDENCE by Design

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